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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,688	10/27/2003	Hong Li	A2778B	8674

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WILEY, REIN & FIELDING, LLP
ATTN: PATENT ADMINISTRATION
1776 K. STREET N.W.
WASHINGTON, DC 20006

EXAMINER	
PRIEBE, SCOTT DAVID	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,688	LI ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☒ Claim(s) *30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 October 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20031027*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The preliminary amendment to the claims filed on 10/27/05 does not comply with the requirements of 37 CFR 1.121(c) as indicated on the notice filed 8/31/05. No response to the notice has been filed, and therefore, as indicated in the notice, the preliminary amendment has not been entered. Thus, claims 1-30 are still pending, and under examination.

Applicant is reminded that in future amendments to the claims, non-entered claims 31-56 should be listed on any complete listing of the claims and the status identified as "not entered." The text of claims 31-56 should not be provided.

Information Disclosure Statement

The information disclosure statement filed 10/27/03 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein as EP 185573, EP253738, and FR272685 has not been considered. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

WO documents 93/00928, 93/00929, 93/15199, 94/26914, 94/28152, 95/02697, 95/18863, 95/21931, 96/01815, 96/17823, 96/22378, 96/25508, and 97/04092 have been considered only with respect to their English abstract and those figures that could be interpreted without supporting text. The copy of reference TB - "Farrell, Recombinant Herpesviruses Lacking Gene for Glycoprotein L, RD#37105A by Cantab Pharmaceuticals Res. Ltd. (1995)" filed in application 09/403,736 was not present in its application file. Thus far, the PTO has been unsuccessful in obtaining a replacement copy of this document. Applicant is requested to provide a copy of this document, if possible, so that it may be reviewed by the Examiner.

Drawings

Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2). To date, only one set of color photographs/drawings has been received, no petition has been filed, and the specification does not contain the required text.

Claim Objections

Claim 30 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not depend form another multiple dependent claim, e.g. claims 26-28. See MPEP § 608.01(n). Accordingly, the claim 30 has not been further treated on the merits.

Claim Rejections - 35 USC § 101 & 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-29 provide for the use of a virus vector in the manufacture of an unspecified medicament, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 26-29 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Since it cannot be determined what process these claims are directed to, they have not been further treated on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 15, and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Tanaka et al. (Nature Med. 3 (4): 437-442, April 5, 1997).

Tanaka discloses a replication-defective adenoviral vector comprising DNA encoding an anti-angiogenic protein, secretable platelet factor-4, under control of a CMV promoter, and a

method for inhibiting growth of a tumor. See entire reference, especially page 439, col. 2 to page 440, col. 1; para. bridging pages 440-441; and page 441, col. 2.

Claims 1, 7, 8, 15, 21, 22, and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Tanaka et al. (Proc. Amer. Assoc. Cancer Res. 38: 264, March 1997).

Tanaka et al. discloses a replication defective adenovirus comprising a sequences encoding angiostatin (which comprises kringles 1-3) under control of a CMV promoter and a method of inhibiting growth of a tumor with the vector.

Claims 1, 2, 15 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhang et al., US 6,143,290, as evidenced by Riccioni et al. (Gene Ther. 5 (6): 747-754, 1998).

Zhang et al. discloses a method for killing tumor cells (which would inhibit their growth) using a replication-defective adenoviral vector comprising a sequence encoding p53 under control of a CMV promoter. See claim 49 for example. Although Zhang does not disclose that p53 is an anti-angiogenic factor, Riccioni et al. discloses that p53 is an anti-angiogenic factor *in vivo*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9, 10, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (Proc. Amer. Assoc. Cancer Res. 38: 264, March 1997) as applied to claims 1, 7, 8, 15, 21, 22, and 25 above, and further in view of O'Reilly et al., US 5,885,795.

Tanaka has been described. Tanaka does not disclose the origin of the angiostatin encoded by the vector, nor does Tanaka disclose that angiostatin expressed from the transgene comprised amino acids 1-333 of plasminogen.

However, O'Reilly describes the treatment of cancer *inter alia* with angiostatin derived from different mammalian sources including human and mouse. O'Reilly focuses primarily on treatment with angiostatin protein, but also teaches that nucleic acid encoding angiostatin may be used in gene therapy, and may be delivered with an adenoviral vector *inter alia*. O'Reilly teaches that human angiostatin had similar anti-angiogenic activity to the mouse angiostatin in a mouse tumor model. O'Reilly describes a construct for expression of angiostatin (Example 23, Fig. 24) where coding sequence for amino acids 1-460 are placed under control of a promoter that was subsequently used for expression of angiostatin from tumor cells. See entire document, especially col. 4, line 40, to col. 5, line 20; col. 6, lines 16-32 and 65-67; col. 8, lines 44-57; col.

11, lines 55-67; col. 12, lines 56-63; col. 13, line 36, to col. 14, line 4; col. 36-37, Example 23; Fig. 24.

Therefore, it would have been obvious to one of skill in the art at the time the invention was made to have used nucleic acid encoding the human angiostatin in the vector of Tanaka since O'Reilly taught that the anti-angiogenic activity of human and mouse angiostatin were similar in a mouse tumor model, and for the nucleic acid to have encoded amino acids 1-460, which comprise amino acids 1-333, because O'Reilly disclosed that such a construct was suitable for expression of angiostatin from tumor cells.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 3, 11, and 16 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 3, 1, and 7, respectively, of prior U.S. Patent No. 6,638,502. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4-6, 12-15, 17-20, and 25 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,638,502. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace the subject matter of the '502 claims, or are directed to embodiments of the '502 claims, that when read in light of the '502 specification are explicitly described as being part of the claimed invention.

Applicant is advised that should claims 7 and 21 be found allowable, claims 8 and 22, respectively, will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 8 and 22 each recite that the angiostatin of claims 7 and 21, respectively,

comprise kringles 1-3. Angiostatin already comprises kringles 1-3 and kringle 4 of plasminogen (spec., page 2, lines 38-40). Consequently, claims 8 and 22 merely recite characteristics inherent of angiostatin, and are identical in scope to claims 7 and 21, respectively.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1633